



PATENT
Attorney Docket No. PC9344B (121*254)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: Ke et al.

Serial No.: 09/736,051

Filed: December 13, 2000

For: COMBINATION THERAPY FOR
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Examiner: Leary, L.

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Assistant Commissioner for Patents
Washington, D.C. 20231

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO: ASST. COMMISSIONER FOR PATENTS, WASHINGTON D.C. 20231 ON THIS 20th DAY OF August 2002.

BY: Jan M. Marshall

REQUEST UNDER 37 C.F.R. § 1.607

Sir:

Applicants respectfully request that an interference be declared between the present application and US Patent No. 6,043,026 ("026 patent") and any pending continuation or divisional application thereof. A copy of the '026 patent is provided herewith as Exhibit 1.

Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, 72-75, 79-80, 84-89 and 92-108 are presently pending. As shown by the Notice of Allowance issued May 21, 2002, the Examiner has found the claims in condition for allowance. Applicants respectfully thank the Examiner for her amendments to the claims in the Notice of Allowability. A copy of all the pending claims is attached as Exhibit 2.

Pursuant to 37 C.F.R. § 1.607(a)(2), Applicants present the following proposed count:

1. Combinations, pharmaceutical compositions, processes of making, and methods of treating or preventing a disease selected from the group consisting of the following:
 - (1) combinations according to claims 1-12 of U.S. Patent 6,043,026; or claims 93-96 of U.S. Application No. 736,051;
 - (2) pharmaceutical compositions according to claims 13-14 of U.S. Patent 6,043,026; or claims 102-105 of U.S. Application No. 736,051;
 - (3) processes for making according to claim 15 of U.S. Patent 6,043,026; or claims 106-108 of U.S. Application No. 736,051; and
 - (4) methods of treating or preventing a disease according to claims 16-21 of U.S. Patent 6,043,026; or claims 97-101 of U.S. Application No. 736,051.

Applicants submit that claims 1-21 of the '026 patent and claims 93-108 of the instant application be designated as corresponding to the proposed count. Claims 93-108 of the instant application are supported by the specification as follows:

Claim 93

A combination that comprises an estrogen agonist/antagonist and a growth hormone secretagogue.

*Page 1, lines 1-3; page 16, lines 10-11;
page 32, lines 26-30.*

Claim 94

The combination of claim 93, wherein the growth hormone secretagogue is 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide or its L-tartaric acid salt.

Page 33, lines 6-8.

Claim 95

The combination of claim 93, wherein the estrogen agonist/antagonist is raloxifene or a pharmaceutically acceptable salt thereof.

Page 5, lines 17-18.

Claim 96

The combination of claim 93, wherein the estrogen agonist/antagonist is (-)-Cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol or a pharmaceutically acceptable salt thereof.

Page 21, lines 31-32.

Claim 97

A method for treating a condition which presents with low bone mass comprising administering to a patient in need thereof a therapeutically effective amount of the combination of claim 93.

Page 4, lines 17-20.

Claim 98

A method for treating a condition which presents with low bone mass comprising administering to a patient in need thereof a therapeutically effective amount of the composition of claim 94.

Page 4, lines 17-20.

Claim 99

A method for treating a condition which presents with low bone mass comprising administering to a patient in need thereof a therapeutically effective amount of the combination of claim 95.

Page 4, lines 17-20.

Claim 100

A method for treating a condition which presents with low bone mass comprising administering to a patient in need thereof a therapeutically effective amount of the combination of claim 96.

Page 4, lines 17-20.

Claim 101

The method of claim 97 wherein the condition is osteoporosis.

Page 4, line 19.

Claim 102

A pharmaceutical composition comprising an estrogen agonist/antagonist, a growth hormone secretagogue, and a pharmaceutically acceptable carrier.

Page 4, lines 17-18; page 16, lines 10-12; page 30, lines 2-4; page 47, line 33 to page 48, line 4.

Claim 103

The composition of claim 102, wherein the growth hormone secretagogue is 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide or its L-tartaric acid salt.

Page 33, lines 6-8.

Claim 104

The composition of claim 102, wherein the estrogen agonist/antagonist is raloxifene or a pharmaceutically acceptable salt thereof.

Page 5, lines 17-18.

Claim 105

The composition of claim 102, wherein the estrogen agonist/antagonist is (-)-Cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydronaphthalene-2-ol or a pharmaceutically acceptable salt thereof.

Page 21, lines 31-32.

Claim 106

A process for making a pharmaceutical composition comprising combining an estrogen agonist/antagonist, a growth hormone secretagogue, and a pharmaceutically acceptable carrier.

Page 48, lines 1-3; page 50, lines 21-25; page 51, lines 3-7 and 19-22.

Claim 107

The process of claim 106, wherein the estrogen agonist/antagonist is raloxifene, (-)-Cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)]-5,6,7,8-tetrahydro-naphthalene-2-ol or a pharmaceutically acceptable salt thereof.

*Page 48, lines 1-3; page 50, lines 21-25;
page 51, lines 3-7 and 19-22.*

Claim 108

The process of claim 106, wherein the growth hormone secretagogue is 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide or its L-tartaric acid salt.

*Page 48, lines 1-3; page 50, lines 21-25;
page 51, lines 3-7 and 19-22.*

As indicated above, claims 93-108 find clear support in the present application. In addition, each corresponds to the proposed count, as does each claim of the '026 patent. It is respectfully submitted that the remaining claims pending in this application, namely claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, 72-75, 79-80, 84-89 and 92, are patentably distinct from the proposed count.

The effective filing date of the instant application, based on U.S. priority patent application No. 60/012,412, is February 28, 1996, which is prior to the effective filing date of the '026 patent. Accordingly, Applicants request that an interference be declared between the instant application and the '026 patent and any continuing or divisional application thereof and that Applicants be declared the senior party.

Serial No.: 09/736,051

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Respectfully submitted,

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